WESTERN GRAIN ELEVATOR ASSOCIATION

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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD
USA, 20852

Dear Sir or Madam:

Re: Docket Number 02N-0278

The Western Grain Elevator Association (WGEA) welcomes this opportunity to provide comment on the proposed rule regarding the prior notice of imported food shipments under *The Public Health Security and Bioterrorism Preparedness and Response Act 2002.*

The WGEA is an organization of nine grain companies operating in Canada that accumulate, store and handle grain grown in Canada. We estimate that our members handle in excess of 90% of Canadian grain exports to the United States collected through approximately 400 facilities in Canada. Our members also import large quantities of U.S. corn and soybean meal. We therefore have a vital interest in ensuring this large and mutually beneficial trade relationship is maintained, and that cross-border shipments continue to flow as smoothly as possible.

WGEA members support the objectives of the bioterrorism legislation. We share the concerns of the United States with respect to preserving a safe and secure food system. In this regard, our members have adopted comprehensive quality management systems, including, in many cases, ISO and HACCP accredited systems. We believe that, except for our concerns noted below, these systems can be adapted to meet the requirements contemplated by the proposed rule.

As an aside, we wish to note that WGEA members support the requirement to register our export facilities as contemplated under the proposed rule for the registration of food facilities (Docket Number 02N-0276). For this reason, we will not be providing comment on that proposed rule, other than to say that we believe the registration of facilities, whether domestic or foreign, will help to protect against possible threats to food security, and will allow for quick notification in case of an emergency. This is a welcome initiative.

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With respect to the proposed regulations regarding the prior notice of imported food shipments, again we can support much of what is proposed. We are concerned however that some measures will impose an onerous cost or administrative burden while doing little, if anything, to enhance food security. We provide the following comments:

Notifying party

Under the proposed rule, the purchaser or importer who resides or maintains a place of business in the United States would be the party required to provide the FDA with the prior notice of the importation of food. In our view, importers should have the option of having the export party provide the notice of shipment to the FDA. The party shipping the product will be in the best position to know the precise product specifications, the expected tonnage, and the expected time of arrival at the port of entry. Relaying this information through the buyer or importer will only serve to increase errors and cause notification delays, potentially resulting in costly shipping delays. This is not a minor concern – for example, the costs imposed by railways for holding back a loaded train are significant. We are convinced a more efficient and reliable system will result if importers have the option of designating, in advance, those exporters that are permitted to provide the FDA with direct prior notice of shipment to their facilities.

Notice period for shipments

Under the proposed rule, notice must be made by noon the calendar day before the day the shipment arrives at the border crossing. Given that the proposed rule requires detailed information on the quantity, product specifications and the arrival time, this lead time requirement is excessive. The nature of the grain business is such that the placement of trucks and railcars at elevator facilities can often vary by several hours, and in some cases days, from the scheduled placement time. Thus the level of precision contemplated under the proposed rule is not consistent with normal commercial practices in the grain trade.

We also note that a noontime deadline means that many notices will be bunched right at that time, with the likelihood for errors (and subsequent amendments) to increase as notifiers scramble to meet the noontime notice deadline. It is our recommendation that companies/shippers provide the required notice 4 hours before the shipment arrives at the border crossing. This will allow for a more even flow of notices, and result in a reduction in documentation errors and a corresponding reduction in the filing of amendments.

Under the proposed rule, the maximum notice period is 5 days, consistent with the maximum allowable period specified in the legislation. We strongly recommend the maximum notice period remain at five days as is proposed, so grain shippers have the flexibility to schedule transportation resources in a manner that ensures shipments mesh well with end user requirements.

Border crossing window

Under the proposed rule, we understand the window for arrival at the border crossing point is up to one hour prior to scheduled arrival or up to three hours beyond scheduled arrival. In our view, this window is much too narrow. As noted above, the timing of train shipments is subject to wide variation, as the time that a locomotive picks up cars from a grain facility is often several hours prior to or beyond schedule. As well, delays in the arrival of trucks at loading facilities often occur due to weather, mechanical breakdown or other causes.

For these reasons, we believe the arrival window must be expanded to allow arrival up to two hours prior to schedule, and up to 24 hours beyond schedule.

Notice provisions for amendments

Many of our grain facilities are located within minutes of the border entry point, either by truck or by rail. Requiring a two-hour minimum notice provision to amend matters such as the precise quantities to be shipped or arrival times, means that trucks and trains could be held up unnecessarily. We recommend that the notice provision for an amendment be reduced to one hour and that more than one minor amendment be permitted on each amendment notice.

Grower Identification

The proposed rule suggests that the identity of the grower and the grower's address, if known, should be included in the notice of shipment. In the case of Canadian grain shipments, we believe the provision of this information is highly impractical, and further, would contribute nothing to reduce the risk of bioterrorism. Typically, grain in any one facility is collected from a multitude of Canadian farmers over a significant period of time, so that a train shipment from one or more facilities would consist of grain from numerous growers. In our view, provision of the list of the names of these growers would be meaningless, and would divert resources that might otherwise be used to adopt meaningful measures to improve food security.

We would simply recommend that, in the case of grain shipments from Canada, notification would only be provided to the FDA if a shipment is known to consist of grain grown in a place other than the United States or Canada. We note that the importation of grain into Canada from non-U.S. sources is rare, and that the subsequent re-export of that grain to the U.S. is rarer still, if it occurs at all.

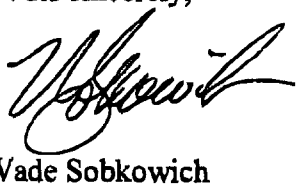
Conclusion

The members of the Western Grain Elevator Association are committed to providing U.S. customers with a high degree of confidence in the safety and security of the products we supply.

The WGEA and its members are willing to cooperate with the FDA in ensuring that the objectives of the bioterrorism legislation are met in a manner that is workable and cost-effective for all parties involved. In this spirit, we respectfully submit these several suggestions as to how the proposed rules might be improved.

Thank you for your consideration.

Yours sincerely,



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Executive Coordinator

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FROM: **Western Grain Elevator Association**

DATE: **April 4, 2003**

5 PAGES, INCLUDING COVER

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